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WILSON SONSINI GOODRICH & ROSATI
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PALO ALTO, CA 94304-1050

EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
02/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,845	HENGST ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *43-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 43(a) and (c), 44-47 and 60, drawn to the native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88 or 89.

Group 2, claim(s) 43(a) and (c), 44-47 and 60, drawn to the native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77.

Group 3, claim(s) 43(a) and (c), 44-47 and 60, drawn to the native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91.

Group 4, claim(s) 43(b), 44-47 and 60, drawn to a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 5, claim(s) 43(b), 44-47 and 60, drawn to a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 6, claim(s) 43(b), 44-47 and 60, drawn to a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 7, claim(s) 43(b), 44-47 and 60, drawn to a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 8, claim(s) 48-51, drawn to a polynucleotide encoding a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 9, claim(s) 48-51, drawn to a polynucleotide encoding a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 10, claim(s) 48-51, drawn to a polynucleotide encoding a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 11, claim(s) 48-51, drawn to a polynucleotide encoding a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 12, claim(s) 52-56, drawn to an antibody that binds specifically to the native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88.

Group 13, claim(s) 52-56, drawn to an antibody that binds specifically to the native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 89.

Group 14, claim(s) 52-56, drawn to an antibody that binds specifically to the native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77.

Group 15, claim(s) 52-56, drawn to an antibody that binds specifically to the native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91.

Group 16, claim(s) 52-56, drawn to an antibody that binds specifically to a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 17, claim(s) 52-56, drawn to an antibody that binds specifically to a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 18, claim(s) 52-56, drawn to an antibody that binds specifically to a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 19, claim(s) 52-56, drawn to an antibody that binds specifically to a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 20, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of the native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88 or 89.

Group 21, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of the native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77.

Group 22, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of the native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91.

Group 23, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 24, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 25, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 26, claim(s) 57-59, drawn to a method of treating anything, including cancer, comprising administering to a patient any amount of a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91, wherein the mutation is any amino acid that cannot be phosphorylated.

Group 27, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of the native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88 or 89 relative to the level of expression of that polypeptide in a normal cell.

Group 28, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of the native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77 relative to the level of expression of that polypeptide in a normal cell.

Group 29, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of the native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91 relative to the level of expression of that polypeptide in a normal cell.

Group 30, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88 relative to the level of expression of SEQ ID NO:2 in a normal cell.

Group 31, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89 relative to the level of expression of SEQ ID NO:2 in a normal cell.

Group 32, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of a

variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77 relative to the level of expression of SEQ ID NO:4 in a normal cell.

Group 33, claim(s) 61-65, drawn to a method of determining whether or not a human cancer cell has the potential for tumor progression, comprising measuring the level of expression of a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91 relative to the level of expression of SEQ ID NO:6 in a normal cell.

Group 34, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88 or 89 relative to other test compositions.

Group 35, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77 relative to other test compositions.

Group 36, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91 relative to other test compositions.

Group 37, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88 relative to other test compositions.

Group 38, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89 relative to other test compositions.

Group 39, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77 relative to other test compositions.

Group 40, claim(s) 66-70, drawn to a method of screening for a composition that inhibits the progression of cancer, comprising exposing aliquots of cancer cells from a patient to various test compositions and selecting a test composition that alters the expression of a variant

polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91 relative to other test compositions.

Group 41, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample.

Group 42, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 89 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample.

Group 43, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample.

Group 44, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample.

Group 45, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample. Presumably, the mutant polypeptide contains at least one native or mutated amino acid at a different position that is phosphorylated.

Group 46, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample. Presumably, the mutant polypeptide contains at least one native or mutated amino acid at a different position that is phosphorylated.

Group 47, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample. Presumably, the mutant polypeptide contains at least one native or mutated amino acid at a different position that is phosphorylated.

Group 48, claim(s) 71-75, drawn to a method of predicting whether or not a patient having discontrol of a tyrosine kinase will respond to a tyrosine kinase inhibitor drug, comprising contacting cells from the patient with an antibody that binds specifically to a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91 and measuring the amount of phosphorylated polypeptide bound to the antibody relative to a reference sample. Presumably, the mutant polypeptide contains at least one native or mutated amino acid at a different position that is phosphorylated.

Group 49, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a native polypeptide of SEQ ID NO:2 in phosphorylated form at at least the Y residue at position no. 88 or 89 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

Group 50, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a native polypeptide of SEQ ID NO:4 in phosphorylated form at at least the Y residue at position no. 77 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

Group 51, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a native polypeptide of SEQ ID NO:6 in phosphorylated form at at least the Y residue at position no. 91 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

Group 52, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 88 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

Group 52, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a variant polypeptide of SEQ ID NO:2 having a mutation at amino acid position no. 89 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that

was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

Group 53, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a variant polypeptide of SEQ ID NO:4 having a mutation at amino acid position no. 77 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

Group 54, claim(s) 76-78, drawn to a method of deriving a candidate agent, comprising contacting cancer cells with the agent, determining the level of expression of a variant polypeptide of SEQ ID NO:6 having a mutation at amino acid position no. 91 in cancer cells that were contacted with the agent relative to the level of expression of that protein in a sample that was not contacted with the agent, comparing the effect of the agent by comparing the two protein levels and deriving the agent from the effect.

The inventions listed as Groups 1-54 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the 54 groups of inventions is a Cip/Kip family protein.

The inventions of Groups 1-54 do not share the common special technical feature of a Cip/Kip family protein, because, as discussed in Applicant's corresponding PCT application, Application No. PCT/EP2004/11860, Cheng et al. ("The $p21^{Cip1}$ and $p27^{Kip1}$ CDK 'inhibitors' are essential activators of cyclin D-dependent kinases in murine fibroblasts," EMBO J 18(6):1571-1583, 1999) disclose the Cip/Kip family proteins of p21Cip1 and p27Kip1 and that these proteins are phosphorylated in vivo, as they are part of signaling pathways involving other proteins (e.g., cyclin D, CDK and ERK's) that are phosphorylated and dephosphorylated at various stages (see, e.g., pp. 1571 and 1579). Not all of the groups listed above are drawn to phosphorylated proteins or methods of using phosphorylated proteins.

Thus, the technical feature of a Cip/Kip family protein does not define the invention over the prior art. Because the common technical feature is not novel (special) with respect to the cited reference, it is clear that the claims of Groups 1-54 lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to multiple products and multiple processes, only a particular combination of which including Group 1 may be considered for unity of invention, i.e., Group 1 and Group 20, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special technical feature is not present, Groups 1 and 20 cannot be considered to have unity of invention.

Regarding the different claimed sequences, Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of the polynucleotides is patentably distinct.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) If Applicant elects Group 1, in claim 44, Applicant must elect the exact set of non-Y residues that are phosphorylated by number of phosphorylated amino acids, identity of phosphorylated amino acids and position of phosphorylated amino acids. This election will be applied to claim 45.

b) If Applicant elects one of Groups 8-11, Applicant must indicate whether the host is a virus, as recited in claim 50, or a mammalian cell, as recited in claim 51.

c) If Applicant elects one of Groups 12-19, Applicant must elect whether the antibody is polyclonal, as recited in claim 55, or monoclonal, as recited in claim 53. It is noted that the antibody from Applicant's hybridoma cell line is claimed in claim 54.

d) If Applicant elects one of Groups 27-33, Applicant must elect in claim 64 the type of cancer cell that is assayed in the claimed method.

e) If Applicant elects one of Groups 34-40, Applicant must elect in claim 68 the type of antibody that is used in the claimed method- a whole antibody, an antibody "derivative," or an antibody fragment. Applicant must elect in claim 69 the type of cancer cell that is assayed in the claimed method. Applicant must also elect in claim 70 the type of tissue sample from which the assayed cells are derived.

f) If Applicant elects one of Groups 49-54, Applicant must elect either claim 77 or claim 78. That is, Applicant must elect whether the candidate agent inhibits the expression of the protein that is a cancer marker (claim 77) or enhances the expression of the protein that is a cancer marker (claim 78).

Applicant is required, in reply to this action, to elect a single species in a) – f) above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 44, 52, 61, 66, 67and 76.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Claims 44 and 45 recite different polypeptide and non-polypeptide molecules, each with a different phosphorylation pattern. Consequently, each molecule has a different structure and different biological and chemical properties. Claims 50-51 recite different hosts, each of which has a different structure and different biological and chemical properties. Claims 53 and 55 recite different antibody mixtures, each of which is a different composition having different components. Claims 64 and 69 recite different kinds of cancer cells, each type corresponding to a different disease, while claims 65 and 70 recite different kinds of samples- in vitro cultures, biopsies, blood or waste. Claim 68 recites different kinds of antibodies, whole, "derivatives," or fragments, i.e., molecules of different structures. Claims 77-78 recite agents that have opposite effects and perform different steps, either increasing or decreasing the expression of a cancer marker protein. Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2009-02-18
/Delia M. Ramirez/
Primary Examiner, Art Unit 1652